K062304
p1/5

510(k) Summary

RTX Healthcare

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92

SEP 29 2006

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Date of summary: 07/07/2006

Common Name: Physiological Transmitter and Receiver
Trade name: DLM112 Daylink Monitor

Classification name: 21 CFR 870.2910 Physiological Signal Transmitter And Receiver.
Classification no: DRG

Predicate Device:
The DLM112 device is substantially equivalent to the following predicate devices:

510(k) number:	K041816
Device name:	RTX3320 Wireless Telehealth Gateway
Applicant:	RTX Healthcare
510(k) number:	K023749
Device name:	M3810A Philips Telemonitoring System with M3812B TeleStation.
Applicant:	Philips Medical Systems.
510(k) number:	K042273
Device name:	Health Buddy with Device Connectivity.
Applicant:	Health Hero Network

Submission Device Description:
The DLM112 telemedicine device performs transmission of physiological patient information to and from wireless, infrared and cabled patient monitors, and a remote data server healthcare facility using standard digital communication technologies and protocols.
The DLM112, with its build-in modem, transmits data using the public switched telephone network.
The DLM112 screen, displays the information or questions about vital signs, symptoms and behaviors sent by the patient's healthcare provider, and allows the patient to respond via four large buttons
The DLM112 device is not used directly on a patient, and poses no significant risk to the patient or other people within the patient's home.

K062304
p 2/5

Intended use and indications for use:
The Daylink 112 Monitor ("DLM112") is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The DLM112 serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.
The DLM112 Monitor does not measure, interpret or make any decisions on the vital data that it conveys.

Substantial Equivalence Comparison table:

Item		**Submission device**	**Predicate device K041816 (RTX Healthcare)**	**Predicate device K023749 (Philips)**	**Predicate device K042273 (Health Hero)**
1	Intended use / Indication for use	See section 2	See section 6	See section 7	See section 8
2	Intended users	Home users and healthcare providers.	Home users and healthcare providers.	Home users and healthcare providers.	Home users and healthcare providers.
3	Site of use	Typically for use in patient's home, placed on a normal table.	Typically for use in patient's home, placed on a normal table.	Typically for use in patient's home, placed on a normal table.	Typically for use in patient's home, placed on a normal table.
4	System description	Telemedicine device that is working as hub/gateway sending measured data from compatible patient monitors to a compatible data server.	Telemedicine device that is working as hub/gateway sending measured data from compatible patient monitors to a compatible data server.	Telemedicine system consisting of a device that is working as hub/gateway sending data measured by the system patient monitors to a system data server.	Telemedicine system consisting of a device that is working as hub/gateway sending data measured by the system patient monitors to a system data server.
5	Connection to patient monitors	Wireless and cable connection between the patient monitors and the hub/gateway.	Wireless connection between the patient monitors and the hub/gateway.	Wireless and cable connection between the patient monitors and the hub/gateway.	Cable connection between the patient monitors and the hub/gateway.
6	Transmission	Residential telephone line	Residential telephone line	Residential telephone line	Residential telephone line
7	Patient Interactions	Display and push buttons for collection of	No patient interaction.	Display and push buttons for collection of	Display and push buttons for collection of

		patient typed data		patient typed data	patient typed data
8	Measurements taken	Blood pressure, weight, ECG, Blood glucose and other measurements provided from compatible monitor devices.	Blood pressure, weight, ECG, Blood glucose and other measurements provided from compatible monitor devices.	Blood pressure, weight, ECG and Blood glucose	Blood pressure, weight, Blood glucose, Peak Flow and others.
9a	Contra indications and warnings	The device is not for emergency calls, and may not be used to send any real-time alarms or time-critical data.	The device is not for emergency calls, and may not be used to send any real-time alarms or time-critical data.	The device does not send any real time alarms.	The device does not send any real time alarms.
9b	Contra indications and warnings	All patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.	Clinical judgment and experience are required to check and interpret the measurements that are taken, collected, and delivered by systems using a RTX3320 device.	Clinical judgment and experience are required to check and interpret the information delivered.	All patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.
9c	Contra indications and warnings	The device is not for use in systems which substitute for medical care.	The device is not for use in systems which substitute for medical care.	The device is not intended as a substitute for medical care.	The device is not to be used as a substitute for a professional healthcare judgment.
9d	Contra indications and warnings	The device is not for use in systems set up for patients who need direct medical supervision or who might need emergency intervention.	The device is not for use in systems set up for patients who need direct medical supervision or who might need emergency intervention.	The device is not for use in systems set up for patients who need direct medical supervision	-No statement-
10	Wireless link between patient monitors and the gateway	Short range radio system using Bluetooth technology.	Short range radio system using Bluetooth technology.	Short range proprietary radio system.	No wireless connectivity

11	Device specifications	See section 5	See section 17	Proprietary information	Proprietary information

Discussion on differences:

Item 1: The intended use / Indications for use for the predicate devices and the submission device are generally the same. The exact use are for all devices limited to be within the same intended use and with respect to the contra indications and warnings which are also generally the same for all three devices.

Item 2: The user of the predicate devices and the submission device is the same. The requirements to the user and skills that the users need to have are the same.

Item 3: Both the predicate devices and the submission device are for use in patient's home. The requirement specifications and the used performance standards for the submission device are defined based on using the device in a home environment.

Item 4: The predicate devices K023749 (Philips) and K042273 (Health Hero) are systems consisting of patient monitor devices, a hub/gateway device and a system server software. The Submission device and the Predicate device K041816 (RTX Healthcare) are a hub/gateway devices with a specified generic protocol interface to a list of compatible patient monitors, and with a specified generic protocol interface to any compatible system server. The protocols for the Submission device and the Predicate device K041816 (RTX Healthcare) are validated against existing compatible patient monitors and servers, and in the labeling it is stated that only compatible patient monitors and servers must be used with the hub/gateway.

Item 5: Two of the predicate devices and the submission device uses wireless communication between the patient monitors and the hub/gateway device. The third predicate device use cable connection which is also available on the submission device.

Item 6: Both the predicate devices and the submission device use a residential telephone line for data communication.

Item 7: The predicate devices K023749 (Philips) and K042273 (Health Hero) are fitted with a display and a few push buttons for patient interaction. The purpose is to interact with the patient to collect additional information. The submission device is also fitted with a display and a few push buttons, and with the same purpose as on the predicate devices.

Item 8: For the predicate devices K023749 (Philips) and K042273 (Health Hero) the measurements taken are defined by the patient monitors that are a part of the system. For the submission device and the predicate device K041816 (RTX Healthcare), the measurements taken are defined by the compatible patient monitors. Because of the similar intended use and indication for use for both the predicate devices and the submission device, the type of measurements will be the same.

Item 9a: Neither the predicate or submission devices may be used to send real time alarms.

Item 9b: Both the predicate and submission devices defines that all patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Item 9c: Both the predicate and submission devices defines that it is not intended as a substitute for medical care or healthcare judgment.

Item 9d: Two of the predicate devices and the submission device state that it is not for use in systems set up for patients who need direct medical supervision.

Item 10: Two of the predicate devices use wireless connectivity like the submission device. One of the predicate devices and the submission device use the Bluetooth wireless technology that are known within medical devices, like the A&D Blood Pressure Meter

(FDA- K043217). The general radio signal safety requirements and FCC Part 15 rules are regulatory requirements that are equal for all devices containing radio transmitter.
Item 11: Detailed environmental specifications are available for one of the predicate devices, but not for the two others since that is proprietary information not available for RTX Healthcare. This is evaluated not to add any additional risks to the patient since both the predicate devices and the submission device, according to the intended use, are designed for use by patients at home. The environmental specifications for the submission device are defined according to IEC/UL 60601-1 and specifications available for other medical devices for home use.

Performance data:

The DLM112 device has been tested to meet the requirements of the following standards and regulations used as acceptance criteria:
IEC 60601-1, IEC 60601-1-2, FCC part 15 and FCC Part 68.
Risk management is performed according to ISO14971:2000.
Based on the fact that the performance comparison of the predicate device and the submission device show that the differences are minor and causes no harm to the user, and the fact that the intended use and indication for use is the same, it was early in the project decided to focus on verification and internal validation instead of large scale validation in form of clinical investigation.
Verification and validation testing activities is conducted to establish performance and reliability characteristics of the device.

Conclusion

The DLM112 is substantially equivalent to the predicate devices cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

RTX Healthcare
c/o Ms. Elizabeth A. Rosenfeld
Administrative Coordinator
KEMA Quality B.V.
4377 County Line Road
Chalfont, PA 18914

Re: K062304
Trade Name: DLM112 Daylink Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: September 14, 2006
Received: September 18, 2006

Dear Ms. Rosenfeld:

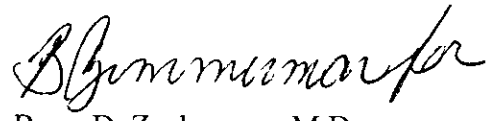
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062304

3. **Indications for use statement**

Indication for Use Statement

510(k) Number (if known):

Device name: DLM112 Daylink Monitor

The Daylink 112 Monitor ("DLM112") is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The DLM112 serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.
The DLM112 Monitor does not measure, interpret or make any decisions on the vital data that it conveys.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062304